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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,153	03/17/2004	Zhi-Jian Yu	AMOINC.001CP1	3939

20995 7590 07/17/2007

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EXAMINER	
SCHLIENTZ, LEAH H	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
07/17/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/802,153	YU ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *18-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 3/2/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1 – 23 are pending, of which claims 18 – 23 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 1 – 17 are readable on the elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/392,375, 11/098,827 and 11/417,891 in view of Noecker (*Adv. Ther.*, 2001, 18, p. 205 – 215). Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims are drawn to a self-emulsifying composition comprising oil globules having a size of less than one micron dispersed in an aqueous phase, said globules comprising a surfactant component consisting essentially of one or two surfactants and a polar oil component. While the '375, '827 and '891 applications do not claim a chlorite component, it would have been obvious to one of ordinary skill in the art to include a chlorite compositions in the compositions of the copending applications because Noecker teaches that preservatives are an important component of ophthalmic preparations, providing antimicrobial activity in the bottle and preventing decomposition of active drug. Stabilized oxychloro complex (SOC) (i.e. a chlorite) causes the least amount of damage to corneal epithelial cells compared to other preservatives. Accordingly, the claims are overlapping in scope and thus are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 contains trademark/trade names, Polyquaternium ® and WSCP ®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe various cationic antimicrobials and, accordingly, the identification/description is indefinite.

Claims 8 and 17 contain the trademark/trade name Lumulse GRH-40. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a surfactant, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 6, 9, 10 and 12 – 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Huth *et al.* (US 2003/0165545).

The instant claims are drawn to a self-emulsifying ophthalmic solution comprising oil globules having an average size of less than one micron dispersed in an aqueous phase, said globules comprising a) a surfactant component consisting essentially of one or two surfactants, a polar oil component and c) a chlorite preservative component.

Huth discloses self-emulsifying compositions for ophthalmic use, such as the care of contact lenses (paragraph 0007 – 0008). The oil-in-water emulsions comprise an oily component, for example, and without limitation, mineral oil; an aqueous component, which includes water; and a surfactant component which includes at least three emulsifiers or surfactants (paragraph 0012). An example of a surfactant may be 10-mole ethylene oxide ether of stearyl alcohol (paragraph 0051 or vitamin E TPGS (paragraph 0137). The compositions may include a chlorite preservative (paragraph 0133), and may include a disinfectant such as Polyquaternium (paragraph 0126) and a therapeutic component (paragraph 0097). Globules of the emulsion must pass through

a 0.22 micron filter (paragraph 0142). It is noted that the instantly composition comprises a) surfactant component consists essentially of one or two surfactants, as well as components b) and c). However, the recitation that the solution comprises components a – c does not exclude further components (i.e. a third surfactant, as claimed by Huth), because the first "comprising" statement (i.e. referring to the composition) is open-ended and precedes the "consisting essentially of" statement (i.e. referring to the surfactant component within the composition), as such the composition may include additional components (i.e. an additional surfactant). This interpretation is supported by claim 5 of the instant application, wherein the composition further comprises an additional surfactant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 3, 6 – 8, 10, 11, 15, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto *et al.* (*Ophthalmology*, 2002, 109, p. 2030 – 2035) in view of Noecker (*Adv. Ther.*, 2001, 18, p. 205 – 215).

Goto discloses low concentration homogenized castor oil eye drops for non-inflamed obtrusive meibomian gland dysfunction (MGD) (abstract). The composition comprises 2% castor oil and 5% polyoxyethylene castor oil which were stirred into distilled water under sterile conditions. The composition forms an emulsion (page 2031). Regarding the claimed size of oil globules in the emulsion, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. Such a limitation, the size of oil globules in the emulsion, is representative of an inherent property of the claimed composition. It is interpreted, in the absence of evidence to the contrary, that the emulsion taught by Goto would inherently have the same sized globules in the emulsion because the emulsion is comprised of the same components as those claimed (i.e. castor oil and POE castor oil). The burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). It is noted that Goto does not specifically recite that his formulation is self-emulsifying, however, the formulation of Goto includes the same components as those which are instantly

claimed (i.e. a castor oil/polyoxyethylene castor oil emulsion); thus the formulation of Goto would inherently be capable of self-emulsifying. It is further noted that Goto uses the term "homogenized" in the description of his eye drops. However, the term does not appear to refer to the method by which the emulsion was prepared (i.e. mechanical homogenization), rather the term refers to the distribution of castor oil in the lipid tear layer which improves ocular surface conditions (page 2034). Regarding claim 16, the instant claims are composition claims and the recitation of the intended use of the composition (i.e. as a "multipurpose solution for contact lenses") has not been patentable weight to distinguish over Goto.

Goto does not teach a chlorite preservative.

Noecker teaches that preservatives are an important component of ophthalmic preparations, providing antimicrobial activity in the bottle and preventing decomposition of active drug. Stabilized oxychloro complex (SOC) causes the least amount of damage to corneal epithelial cells compared to other preservatives. Physicians should consider treatment with preparations containing low-risk preservatives, such as SOC, especially in patients receiving multiple ophthalmic medications (abstract).

Noecker does not teach self-emulsifying compositions comprising a surfactant and polar oil component.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to include a preservative such as SOC in the eye drops of Goto because Noecker teaches that such preservatives provide the advantage of providing antimicrobial activity in the bottle of ophthalmic formulations. One would have been

motivated to do so, and would have had a reasonable expectation of success in doing so, because Noecker teaches that SOC has a low toxicity compared to other preservatives.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER